Mobilizing Pediatric Subspecialists to Inform Regulation: A 5-Step Case Study to Reduce Consumption of Added Sugars

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Pediatricians and pediatric subspecialists are poised to shape health policy and to advocate for population-level health transformation.[1] Their training in science, coupled with their provider experiences witnessing firsthand effects of health policy, equip them to be knowledgeable and trusted voices for policy advocacy.[2] Moreover, by informing policy, they may also experience increased professional fulfillment and belonging.[3,4] Children, who often cannot speak on their own behalf, warrant special protection.[5] Further, the consequences of failed social policies often manifest first in adverse outcomes for children,[6] whose formative years are especially sensitive to experiences that influence lifelong health and well-being.[7]

Regulations are directives that are established, implemented, and enforced by federal agencies. To address competing interests, Congress established a process by which regulations and regulatory changes must include public notice and comment.[8] As such, federal agencies use this process to formally publicize and solicit feedback from the public during a ~30-60 day window. Agencies are mandated to consider these comments, which can correct errors, suggest alternative language, provide data or expertise, and share experiences that highlight real-world impact.[9] All submissions are analyzed by a computer program to assess similarity based on a scale of shared characters (Food and Drug Administration [FDA] Dockets Management, personal communication, April 17, 2024). Subsequent steps vary depending on the type of comment submission activity (eg, draft guidance, proposed rule, public meetings) (Center for Science in the Public Interest, personal communication, email, April 19, 2024). By participating, individuals and organizations can help shape more effective, equitable policies and ensure that decision-makers understand the consequences of proposals.[9]

There are several instances relevant to child health. For example, the Environmental Protection Agency updated the Lead and Copper Rule in 2024, which improved protections for children from lead in drinking water.[10] Similarly, the FDA guidance on pediatric drug development requires studies to ensure medications are safe and effective for children.[11]

Public comments influence regulatory decisions through their volume, personalization, and evidentiary strength. Although the process is not intended to function as a vote, identical or similar comments are considered in aggregate, and agencies can revise proposals in response to high comment volume.[12] Substantive, fact-based, and personalized comments, especially from professional organizations,[13] carry the most weight and can drive meaningful regulatory changes.[14,15] The public comment process can also successfully contribute to regulatory modifications that guide policy implementation.[16] In this way, public comments allow physicians to translate their knowledge and frontline clinical experience into meaningful regulatory outcomes.[17]

Stanford Medicine Children's Health's Office of Child Health Equity (OCHE) established the Health Equity Alliance (HEA) to unify pediatric subspecialities in advancing child health equity through community engagement and policy participation. One strategy the HEA employs is leveraging its subspecialist network to comment on child-relevant health regulations.

In 2023, the FDA solicited public comment on consumption of added sugars, or sugars added to foods and beverages during their processing, as part of a broader initiative to address chronic diseases. Although prior efforts have contributed to a modest decline in consumption,[18] added sugars intake still exceeds Dietary Guidelines for Americans' recommended limits.[19] Given the HEA's pre-existing infrastructure for informing policy, this FDA opportunity presented a unique way for OCHE to mobilize pediatric health care providers, including physicians and advanced practice providers. This case study established a 5-step process for mobilizing subspecialists to inform child health regulations.

FDA	Food and Drug Administration
HEA	Health Equity Alliance
OCHE	Office of Child Health Equity

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Five-Step Process for Engaging Pediatric Subspecialists to Inform Regulation

Step 1. Engaging with Policy Experts

The initial step involved consultations with policy experts to identify effective comment submission strategies. In this case, OCHE connected with child nutrition advocates and policy experts. This included the University of California's Nutrition Policy Institute, which conducts and translates policy-relevant nutrition and health research, and the Center for Science in the Public Interest, a nationally recognized nutrition advocacy organization. These partners helped align OCHE's initiative with national efforts and collective public health messaging.

Step 2. Identifying Scholars to Develop Evidence-Based Recommendations

To ensure comments were backed by credible evidence, we collaborated with subject-matter experts who provided evidence-based language tailored to the regulatory topic. OCHE coordinated with Stanford child nutrition research experts, a clinical dietician, and a medical student to curate templates on 4 key strategies for reducing added sugars intake deemed as key priorities: instituting front-of-package labels, reducing added sugars in school meals, combatting misleading health claims, and decreasing use of non-nutritive sweeteners as a substitute for added sugars. Each letter included evidence summarizing the relevance of each topic on added sugars consumption and provided a tailored regulation recommendation.

Step 3. Developing an Efficient Comment Submission Process

A high volume of similar comments can signal widespread support or opposition, but thoughtful, unique submissions carry the most influence on rule changes. A streamlined system for generating, customizing, and submitting comments allowed us to maximize the quantity of comments submitted while incorporating unique patient stories that make the pediatrician's perspective valuable. OCHE streamlined the process for creating the final, personalized letters using Qualtrics, a survey platform that enables data collection and analytics. Respondents chose one of the 4 templated letter topics and based on their preferred choice, the survey displayed the template for customization by adding de-identified patient stories, personal anecdotes, or additional evidence. Microsoft Word mail merge generated these unique letters for each individual with their name, title, and role. Letters were reviewed for HIPAA compliance. Based on early feedback from users, writers could indicate interest in reviewing their final letter before submission. The Institutional Review Board deemed this project exempt.

Step 4. Obtaining Institutional Approval

Many institutions have policies governing employee advocacy with government relations or an external affairs department frequently responsible for oversight. OCHE met with the institution's Chief Government Relations Officer throughout the process. This institutional approval was critical in ensuring letters were submitted on behalf of individuals and not the institution.

Step 5. Promoting the Comment Opportunity

Because both the volume and quality of comments can influence regulatory decisions, it is critical to identify effective ways to engage potential contributors and provide them with background on the regulatory process, the importance of public comments, and the specific issue under consideration. OCHE presented this opportunity to pediatric subspecialists at division meetings and at the Pediatrics Residency Program Morning Report. Presentation content included background on the health implications of excessive consumption of added sugars, the regulatory participation process, and the specifics of the FDA public comment opportunity.

Outcomes

This pilot demonstrated how pediatric subspecialists can meaningfully contribute to the public comment process. The following characteristics (Table I) reflect factors that can influence whether comments are noticed and considered in regulatory decision-making.

Comment volume: A total of 65 comments were submitted, representing 16% of all 418 comments submitted nationwide to the FDA docket on strategies to reduce added sugars.

Unique comments: Of the 65 submissions, 37 (57%) were unique, meaning they included a personal story, additional evidence, or both, rather than simply using the unmodified template.

Topic variety: Comments addressed one of the 4 topics: added sugars in school meals (41, 63%); deceptive and misleading health claims (10, 15%); front-of-package labels (10, 15%), and non-nutritive sweeteners (4, 6%).

Patient stories: Nearly half of all comments (32 letters, 49%) included a de-identified patient story. These narratives provided real-world examples of how excessive added sugars intake affects diverse pediatric populations, from early-onset fatty liver disease to complications in cancer survivors (Table II).

Evidence: Seven comments (11%) incorporated additional scientific references or data beyond the provided template.

Lessons Learned

The goal of this pilot was to develop a system to help busy pediatric subspecialists submit public comments that maximize their influence on regulatory decisions. Comments are most compelling when they pair scientific evidence with on-the-ground stories, address a diverse range of topics, and introduce considerations that policymakers might otherwise

Table I. Characteristics of public comments submitted to Food and Drug Administration (FDA) docket no. FDA-2023-N-3849

Total comments submitted nationally (n = 418)	N (%)
Non-Office of Child Health Equity (OCHE) comments	353 (84%)
OCHE comments	65 (16%)
Characteristics of OCHE comments (n = 65)	**N (%)**
Inclusion of evidence	
Yes	7 (11%)
No	58 (89%)
Inclusion of personal story	
Yes	32 (49%)
No	33 (51%)
Comment topic	
Added sugars in school meals	41 (63%)
Deceptive and misleading health claims	10 (15%)
Front-of-package labels	10 (15%)
Nonnutritive sweeteners	4 (6%)
Commenter role	
Faculty	27 (42%)
Dietitians and nutrition specialists	18 (28%)
Residents and trainees	13 (20%)
Staff	7 (11%)
Commenter division	
Gastroenterology, hepatology, and nutrition	22 (34%)
General pediatrics	11 (17%)
Pediatric residents and trainees	11 (17%)
Endocrinology and diabetes	9 (14%)
Developmental-behavioral pediatrics	6 (9%)
Adolescent medicine	4 (6%)
Hematology, oncology, stem cell transplantation & regenerative medicine	1 (2%)
Neonatal and developmental medicine	1 (2%)

overlook. This pilot revealed valuable lessons that can be applied to future efforts.

Humanize Evidence with Stories from Pediatric Providers across Subspecialties

Although evidence can inform effective change, patient stories bring data to life.[20] Pediatric subspecialists form trusting relationships with families, generating a repository of rich patient stories relevant to child health policies. These stories move beyond abstract statistics to capture lived experiences, highlighting tangible benefits or drawbacks of proposed policies. As an example, one commenter described their five-year-old patient with severe obesity. Her parents believed she ate healthy snacks, but were shocked to see how much added sugar they contained after reviewing the labels. As the pediatrician explained, warning labels on high-sugar foods could equip families to make healthier choices. Such stories underscore the breadth of health consequences across subspecialties and provide concrete examples of regulatory changes and their potential impact.

Leverage Researchers' Expertise

Partnering with subject-matter experts ensures that public comments are grounded in rigorous evidence and real-world clinical experience. Early engagement with academic researchers or professional societies can leverage up-to-date data and strengthen submission credibility. This is particularly important because public health opponents are more likely to submit comments with non–peer-reviewed sources or research sponsored by organizations with conflicts of interest.[21]

Leverage Expertise of Policy Experts

Translation of evidence into policy requires policy experts' insights.[22] OCHE partnered with nutrition policy experts to gather important details on the FDA's comment submission process, glean effective strategies for comment submission, and understand the feasibility of proposed solutions from the regulatory agency's perspective. Pediatric institutions without dedicated governmental affairs infrastructure can collaborate with professional organizations (eg, American Academy of Pediatrics, Academic Pediatric Association), many of which have dedicated policy councils and local chapters.

Partner with the Appropriate Institutional Department

Regardless of its size, most children's hospitals have a designated department or staff member responsible for the management of relationships with governmental officials or oversight of employees seeking to inform policy. Indeed, most health care systems state that unless specifically authorized, employees should not represent their personal views as the official stance of their employer or affiliated organization. Longstanding relationships and partnerships with the Stanford Medicine Children's Government Relations were key in ensuring this pilot complied with institutional policies.[23] In this case, we received necessary approvals and our template letters included standardized language indicating the letter was submitted on behalf of the individual and not the institution.

Activate Existing Networks

Policy action often has a small window of opportunity. Thus, utilizing existing institutional channels (eg, clinical education meetings department/division meetings, email lists, newsletters) to reach contributors is critical. In this case, established relationships across subspecialty divisions enabled rapid mobilization, with champions in each division promoting the initiative through their professional networks and existing communication platforms.

Balance Efficiency and Personalization

The inherent tension between efficiency and personalization of comments requires careful balance. Impactful comments often contain a story that is coupled with evidence. However, busy subspecialists with competing priorities have limited time to draft impactful letters, creating a barrier to participation. Moreover, the process may be unfamiliar for those with no previous experience. This pilot aimed to balance efficiency and personalization by using an automated system to provide templated letter drafts that allowed for customization

Table II. Examples of personal stories submitted by subspeciality pediatric divisions to Food and Drug Administration (FDA) docket no. FDA-2023-N-3849

Pediatric division	Topic	Personal story
Adolescent medicine	Balanced-eating	"As an expert in eating disorders, I support an "all foods fit" model to encourage healthy, balanced eating. I've taken care of many patients who were not engaging in healthy eating habits, with some of that being unknown to them due to added sugars. Reducing added sugars will help my patients and their families achieve this way of balanced eating."
Developmental behavioral pediatrics	Low-calorie school meals	"I take care of children with neurodevelopmental disorders, including genetic conditions, neurological injuries, and intellectual disabilities. These children may have difficulty regulating their intake. They may also have difficulty with mobility and therefore do not burn calories as effectively as their typical peers. When they become obese, they are at increased risk of obstructive sleep apnea, which in turn robs them of concentration, memory, and other skills. So, lowcalorie school lunches are essential to avoid this terrible cycle."
Endocrinology and diabetes	Added-sugar labeling	"Almost every week during my diabetes and endocrine clinics I see a referral for pediatric obesity from community doctors wondering if there is an endocrine cause for a child < 5 to be obese. One of them is…a 5 year old who weighs 28 kg > 99% for a child her age... During her visit, the parents expressed that she eats a healthy diet, with childhood appropriate snacks...Upon review of the sugar content of these "healthy" snacks, parents expressed not realizing that they were not as healthy or that they had that much sugar. Proper warning and labeling of high sugar containing foods would make a huge difference in families like this patient who I see on weekly basis."
Gastroenterology, hepatology, and nutrition	Pediatric fatty liver disease	"As a pediatric liver physician and specialist, I have increasingly seen very young children presenting with fatty liver disease. Fatty liver disease is the number one indication for adult liver transplant in the United States due to cirrhosis. The younger children develop fatty liver disease, the earlier their risk is of developing advanced liver disease requiring a life altering liver transplant. I am referring children earlier and earlier to obesity clinics where they may move into consideration for bariatric surgery for complications of their obesity. I am also seeing children younger and younger with near cirrhosis (the most scar you can have of the liver). Addressing added sugars will help to get to the upstream issue and one of the causes of this epidemic."
General pediatrics	Added-sugar labeling	"As a pediatrician in the community working largely with families on Medicaid, I can't stress enough how important healthy options are. My families are trying to provide healthy food to their kids, like yogurt or "toddler milk" without realizing that these products contain a very unhealthy amount of added sugar."
Pediatric hematology, oncology, stem cell transplantation & regenerative medicine	Added-sugar labeling	"As a pediatric oncologist caring for many low-income, non-English language preferred families of children with cancer and teen/young adult survivors of childhood cancer, I see firsthand the importance of clear nutrition labeling to promote long-term health. Many childhood cancer treatments place survivors at increased risk of obesity, diabetes, high blood pressure, and early cardiovascular disease. Healthy nutrition is an essential preventive measure that can help reduce the long-term risk of morbidity and mortality. Many families who prefer a language other than English struggle to read and understand food labels. Flagging foods with front-of-package labeling would significantly improve these families' abilities to choose healthier foods and as a result, improve childhood cancer survivors' long-term health."
Pediatric residents and trainees	Deceptive marketing	"Another public health concern that has resurged recently is the broad availability of chocolate milk in school cafeterias, in conjunction with reinvigorated campaigns by Big Milk corporations to market chocolate milk as an "energy drink." They have gone so far as to leverage chocolate milk as a way to "empower young female athletes," which is endangering the health of all children who rightfully aspire to make physical activity a part of their lifestyle. I have seen many children who struggle with hyperlipidemia, hyperglycemia, and other metabolic disorders who are endorsing this flawed, dangerous perspective because of how easily accessible chocolate milk and its promotional campaigns have become."

through the addition of further evidence and/or patient stories. Automation also enabled the tracking and reviewing of letters prior to submission. Artificial Intelligence may also be leveraged to streamline the process.

Understand How Comments Inform Regulatory Change

This case revealed the understandings regarding the process and outcomes of regulatory public comment submissions. In this case, a FDA Dockets Management Office representative noted that of the 418 total comments submitted to the added sugars docket, 256 were 95% or more identical, 41 comments were 90-99% identical, leaving only 79 comments being classified as unique (FDA Dockets Management, personal communication, April 17, 2024). Unique comments are then examined for their viewpoints. Thus, when utilizing letter templates, personalization with stories or additional evidence would likely garner more weight.

This case also highlighted specific procedures for reviewing comments, responding to recommendations, and publishing responses. The FDA released a summary of themes heard during its listening sessions, but as of this writing, responses

to public comments from the FDA's public meeting on added sugars have yet to be released.[24]

Comments can also be used to inform future guidelines and regulatory actions. In January 2025, the FDA proposed a rule on front-of-package nutrition labeling (closed for comment on July 15, 2025 after a 60-day extension) that would require standardized packaged food nutrition disclosures for whether they are "high," "medium," or "low" in sodium, added sugars, and saturated fat.[25] In addition to research and focus groups, development of the rule was informed by a public meeting and listening sessions.

Conclusions

In this case study, using a structured process helped pediatric subspecialists submit public comments that included evidence and stories—key elements valued by regulators. One limitation is that we did not fully explore the perspectives of pediatric subspecialists and regulators related to this process informing regulation. In a current regulatory public comment opportunity, OCHE is conducting semi-structured interviews with commenters to understand their experiences of the process.

Although this initiative focused on added sugars, the approach is adaptable to a range of child health issues requiring regulatory input. Further, this process may build the capacity of busy clinicians to inform regulatory advocacy, thus adding real-life experience to the evidence base for rule-making. Future work could explore technology-driven innovations and evaluate how such comments, particularly those with patient stories, are weighted in regulatory decision-making. Efforts could also assess how participation affects subspecialists' sense of institutional engagement, cross-specialty relationships, and personal agency. ■

CRediT authorship contribution statement

Jang Lee: Writing – review & editing, Writing – original draft, Investigation, Formal analysis. **Eimaan Anwar:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Alison Clayshulte:** Writing – original draft, Investigation. **Lisa J. Chamberlain:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization. **Janine Bruce:** Writing – review & editing, Methodology, Conceptualization. **Noelle H. Ebel:** Writing – review & editing. **Christina Hecht:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Conceptualization. **Adrienne Lazaro:** Writing – review & editing, Methodology, Conceptualization. **Shweta S. Namjoshi:** Writing – review & editing, Writing – original draft, Resources, Methodology, Conceptualization. **Anisha I. Patel:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Declaration of Competing Interest

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